K071398

OCT 4 2007

applied **Spectral Imaging**
Bringing the Details to Light

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name
Proprietary Device Name: ScanView

Establishment Name and Registration Number of Submitter

Name:	Applied Spectral Imaging Ltd. (ASI hereafter)
Registration:	9615060
Submission contact:	Dan Laor
	4 Hamatechet
	Ramat Gavriel, 10551
	Israel
	Tel: +972-4-6547567 x 246

Device Classification

Product Code:	JOY
Regulation Number:	21 CFR 864.5260
Common Name:	Automated cell-locating device
Regulation Description:	Automated fluorescence in situ hybridization (FISH) enumeration systems
Regulatory class:	Class II

Reason for 510(k) Submission
Traditional 510(k) Submission

Identification of Legally Marketed Equivalent Devices
FISHView K050236 and CytoVision CEP XY K042542

Device Description
The ScanView System is an integrated digital imaging system constructed of an external microscope, motorized multi slide stage, camera, and a workstation. It is designed to acquire images of cells and enables identification and examination of cells of interest. Cytogenetics experts can view and scan cells and record the image, using both bright field and fluorescent illumination. The acquired images can be enhanced, archived, retrieved and printed. The automated microscope enables Z motion of the slide and the motorized stage enables its X-Y motions. The microscope also includes motorized filter turret containing fluorescence filters.

Indications for use
The ScanView is an automated scanning microscope and image analysis System. It is intended for in-vitro diagnostic use as an aiding tool to the pathologist or cytogeneticist in the detection, classification and enumeration of cells of interest based on color, intensity, size, pattern, and shape. The ScanView is indicated to detect the following cell types: CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe kit (Vysis, Inc. Downer's Grove, IL) and is limited to the analysis of CEP XY probes via high magnification capture and analysis of interphase nuclei. CEP XY is indicated for use to assess the effectiveness of bone marrow transplantation in opposite-sex transplants.

Safety & Effectiveness

The device has been designed, verified and validated complying with 21CFR 820.30 regulations. Bench and clinical data demonstrate that the device meets the required specifications. No adverse effects have been detected.

Substantial Equivalency

It is Applied Spectral Imaging Ltd.'s opinion that the ScanView System is substantially equivalent in terms of safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Applied Spectral Imaging, LTD
c/o Ms. Silvia Stolarski
Regulatory Affairs Officer
4 Hamatechet
Ramat Gavriel, 10551
ISRAEL

AUG 26 2011

Re: k071398
Trade/Device Name: Scanview, Model SC-300
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: Class II
Product Code: JOY
Date: May 13, 2007
Received: May 21, 2007

Dear Ms. Stolarski:

This letter corrects our substantially equivalent letter of October 4, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

applied Spectral Imaging
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Indications for Use

510(k) Number (if known): K071398

Device Name: ScanView

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Prescription Use: YES (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use: NO (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K071398